Lipocine to Present LPCN 1148 and LPCN 1144 at the EASL Congress 2023

Phase 2 proof-of-concept study of LPCN 1148 in male cirrhotic patients with sarcopenia is fully enrolled with topline 24-week results expected mid-2023

SALT LAKE CITY, June 7, 2023 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company focused on treating Central Nervous System (CNS) disorders by leveraging its proprietary technology platform to develop differentiated products, today announced that it will present posters on LPCN 1148 and LPCN 1144 at the forthcoming European Association for the Study of the Liver (EASL) Congress 2023, to take place in Vienna, Austria, June 21 – 24, 2023.

A multimodal treatment candidate for sarcopenia in men with decompensated cirrhosis: a randomized, placebo-controlled trial evaluating LPCN 1148

Lead author and presenter: Dr. Benjamin J. Bruno, Senior Director of Clinical Development at Lipocine
Session: Cirrhosis and its complications: Other clinical complications except ACLF and critical illness
Date and Time: Wednesday, 21 June, 9:00 am CEST
Room: Poster Area
Poster ID: WED-358

Efficacy and safety of LPCN 1144 in hypogonadal and eugonadal subjects for the treatment of nonalcoholic steatohepatitis (NASH) with fibrosis

Lead author and presenter: Dr. Benjamin J. Bruno, Senior Director of Clinical Development at Lipocine
Session: NAFLD: Therapies
Date and Time: Friday, 23 June, 9:00 am CEST
Room: Poster Area
Poster ID: FRI-466
Selected for Poster Tour presentation

Dr. Bruno will give a live presentation of this poster followed by a Q&A session during the Poster Tour on June 24th at 15:30-16:15 at the Metabolism, Alcohol, and Toxicity Track hub.

The posters will be available on Lipocine's corporate website following the meeting.

About LPCN 1148

LPCN 1148 is a novel androgen receptor agonist prodrug for oral administration with compelling multi modal action to improve liver and muscle function, resulting in improved quality of life while awaiting liver transplant, decreased hospital admissions, and prevention or reduction in occurrence and recurrence of decompensation events.

About LPCN 1144

LPCN 1144, a novel androgen receptor agonist prodrug for oral administration, is being developed as a treatment for pre-cirrhotic non-alcoholic steatohepatitis (NASH) and recently completed a Phase 2 paired biopsy clinical study (LiFT or Liver Fat intervention with oral Testosterone).

About Lipocine

Lipocine is a biopharmaceutical company leveraging its proprietary technology platform to augment therapeutics through effective oral delivery to develop products for CNS disorders. Lipocine has drug candidates in development as well as drug candidates for which we are exploring partnering. Our drug candidates represent enablement of differentiated, patient friendly oral delivery options for favorable benefit to risk profile which target large addressable markets with significant unmet medical needs.

Lipocine's clinical development candidates include: LPCN 1154, oral brexanolone, for the potential treatment of postpartum depression, LPCN 2101 for the potential treatment of epilepsy and LPCN 1148, a novel androgen receptor agonist prodrug for oral administration targeted for the management of symptoms associated with liver cirrhosis. Lipocine is exploring partnering opportunities for LPCN 1107, our candidate for prevention of preterm birth, LPCN1154, for rapid relief of postpartum depression, LPCN 1148, for the management of decompensated cirrhosis, LPCN 1144, our candidate for treatment of non-cirrhotic NASH, and LPCN 1111, a

once-a-day therapy candidate for testosterone replacement therapy (TRT). TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate developed by Lipocine, is approved by the FDA for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism, in adult males. For more information, please visit www.lipocine.com.

Forward-Looking Statements

This release contains "forward-looking statements" that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and include statements that are not historical facts regarding our product development efforts, the application of our proprietary platform in developing new treatments for CNS disorders, our product candidates and related clinical trials, and the potential uses and benefits of our product candidates. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks that we may not be successful in developing product candidates to treat CNS disorders, we may not have sufficient capital to complete the development processes for our product candidates, we may not be able to enter into partnerships or other strategic relationships to monetize our non-core assets, the FDA will not approve any of our products, risks related to our products, expected product benefits not being realized, clinical and regulatory expectations and plans not being realized, new regulatory developments and requirements, risks related to the FDA approval process including the receipt of regulatory approvals and our ability to utilize a streamlined approval pathway for LPCN 1154, the results and timing of clinical trials, patient acceptance of Lipocine's products, the manufacturing and commercialization of Lipocine's products, and other risks detailed in Lipocine's filings with the SEC, including, without limitation, its Form 10-K and other reports on Forms 8-K and 10-Q, all of which can be obtained on the SEC website at www.sec.gov. Lipocine assumes no obligation to update or revise publicly any forward-looking statements contained in this release, except as required by law.

SOURCE Lipocine Inc.

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